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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/441, 936 11/17/99 BARDY

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EXAMINER

DROESCH, K

ART UNIT

PAPER NUMBER

3762

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/441,936 | BARDY ET AL. |
| Examiner | Art Unit | |
| Kristen L. Drosch | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 20 and 21 is/are allowed.
- 6) Claim(s) 1,2,5,6,10-15 and 17-19 is/are rejected.
- 7) Claim(s) 3-4, 7-9, and 16 is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

| | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 10, 12, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219). Adams et al. shows an atrial defibrillator (30) comprising a housing (32); a shock generator (76) disposed in the housing and operable to shock the patient; and an analyzer (62) disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal if the patient is experiencing atrial defibrillation, and to enable a shock generator (76) if needed.

Although Adams et al. does not show a portable, non-implantable housing and a pair of defibrillator pads coupled to the shock generator, Adams et al. teaches an alternative embodiment of an external atrial defibrillator with pad electrodes (Col. 8, lines 33-43). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the external atrial defibrillator with external electrode pads that Adams et al. teaches for the implanted atrial defibrillator with leads that Adams et al. shows, wherein so doing would amount to mere substitutions of one functional equivalent for another that would work equally well on the Adams et al device.

Regarding claim 2, Adams et al. shows that the device further comprises a control device (72) disposed in the housing (32) and coupled to and operable to activate the shock generator (76).

With respect to claims 10 and 18, Adams et al. further shows the analyzer is further operable to determine from the cardiac signal whether the atrial fibrillation terminates after the shock generator shocks the patient (Col. 7, lines 44-60).

Regarding claims 12 and 19, Adams et al. further shows the cardiac signal comprises an electrocardiogram that includes an R wave having a rising edge and the analyzer is operable to enable the shock generator during the rising edge of the R wave and to disable the shock generator outside of the rising edge (Col. 8, lines 10-22).

3. Claims 5, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. Ferrari (5,824,033). Although Adams et al. does not show or teach the defibrillator pads are capable of receiving the cardiac signal, electrode pads that are capable of both delivering a defibrillation pulse and receiving ECG signals are well known (See Ferrari US Pat No. 5,824,033). Therefore it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize defibrillation/sense electrodes for the electrodes of Adams et al. since they are well known and would have the added benefit of eliminating additional parts.

4. Claims 6, 11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. in view of Olson et al. (6,141,581). Adams et al. is as explained before. Adams further teaches that the analyzer (62) measures the duration of the R-R intervals when determining if a patient is experiencing atrial fibrillation when one of the calculated differences exceeds the threshold. Although Adams does not teach that the analyzer measures and compares the respective differences between the lengths of contiguous R-R intervals, attention is directed to Olson et al. who teaches of an analyzer which measures and compares the respective differences between contiguous R-R intervals in order to

determine if atrial defibrillation is occurring in a patient (Col. 15, lines 23-46). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the analyzer of Olson et al. for the analyzer of Adams et al. wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Adams et al. device.

Allowable Subject Matter

5. Claim 20-21 are allowed. The prior art of record fails to teach or suggest restricting access to the shock generator of an external defibrillator to an identified operator.
6. Claims 3-4, 7-9, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 3-4, the prior art of record fails to teach or suggest precluding the patient or an unauthorized user from accessing the shock generator of an external defibrillator.

With respect to claim 7, the prior art of record fails to teach or suggest measuring the R-R interval durations of a first and second group, calculating the differences between the durations of contiguous R-R intervals in each group, comparing these two groups respectively, and determining that atrial fibrillation has occurred if one of the first group differences and one of the second group differences exceed a threshold.

Regarding claim 8, the prior art of record fails to teach or suggest calculating and comparing a QRS difference to a stored QRS threshold in addition to the R-R interval

measurement, difference calculation, and comparison to a threshold in order to determine atrial fibrillation (the specifics given in claim 6).

With respect to claim 9, the prior art of record fails to teach or suggest measuring and determining if a patient's heart rate is within a predetermined range in addition to the R-R interval measurement, difference calculation, and comparison to a threshold in order to determine atrial fibrillation (the specifics given in claim 6).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Alt (6,181,967) shows an external defibrillator for atrial fibrillation with internal catheter leads.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L. Drosch whose telephone number is 703-605-1185. The examiner can normally be reached on 10:00-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Drosch
kld
June 15, 2001


KENNEDY SCHAETZLE
PRIMARY EXAMINER
6/15/01